MAR 1 9 2002

K010253

510(k) Summary of Safety and Effectiveness in Accordance with SMDA'90

December 12, 2000

Transonic Systems Inc.
34 Dutch Mill Road
Ithaca, NY 14850
Telephone Number : (607) 257-5300
Fax : (607) 257-7256

Establishment Registration Number: 1319030

Contact: Mark S. Alsberge

Product Name: Transonic Angio Flow Meter and Catheter

Trade Name: Thermodilution meter and catheter

Classification name:

Cardiovascular Blood Flowmeter
Cardiovascular
Class II, 74 DPW
21 CRF *§870.2100*

SUBSTANTIAL EQUIVALENCE[1] TO:

510 (k) Number	Name	Applicant
K960817	Transonic HD01 – Series Hemodialysis Monitor	Transonic Systems Inc.
K872770	Dual-Thermistor Thermodilution Catheter & Infusion Catheter	Submitted by: Nova Medical Specialties 449 Oakshade Road Indian Mills, NJ 08088 Now owned and operated as: B. Braun Medical, Inc. 18 Olney Ave., Bldg. #44 Cherry Hill, NJ 08003 -1607

Device Description:

In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, Transonic Systems Inc. intends to introduce into interstate commerce the Transonic Angio Flow Meter and Catheter which is intended for the measurement of blood flow within a vascular bed utilizing a catheter-based sensor. This sensor system uses thermal changes induced by a bolus injection of normal saline and thermal-dilution principles to calculate blood flow in hemodialysis grafts.

Indications for Use:

The Transonic Angio Flow Meter and Catheter indicated for use during angioplasty procedures to verify the flow before, during and after treatment. The system is intended for the measurement of blood flow within a vascular bed utilizing a catheter-based sensor. This sensor system uses thermal changes induced by a bolus injection of normal saline and thermal-dilution principles to calculate blood flow.

Material:

The Transonic Angio Flow Catheter is composed of materials that are identical to the predicate device. The patient contacting materials have been tested in accordance with the EN Standard 30993 and/or USP class VI and are suitable for the intended use of this product. They have a long history of safe use in the predicate catheter.

Biocompatibility is not applicable to the meter component of the system. The meter has been tested to meet the applicable electrical safety requirements in accordance with the IEC 601 series of standards.

Substantial equivalence:

The Transonic Angio Flow Meter is similar in materials, form and intended use to the Transonic HD01 - Series Hemodialysis Monitor currently marketed by Transonic Systems Inc. and cleared under K960817.
The Transonic Angio Flow Catheter is similar in materials, form and intended use to the Dual-Thermistor Thermodilution Catheter & Infusion Catheter currently marketed by B. Braun Medical Inc. and cleared under K872770.
There are no new issues of safety or effectiveness raised by The Transonic Angio Flow Meter and Catheter.

Safety And Effectiveness:

All finished products are tested and must meet all required release specifications before distribution. The array of testing required for release includes, but is not limited to; physical testing, visual examination (in process and finished product).

The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures and parameters which conform to the product design specifications.

The testing instruction records for each of the individually required procedures are approved, released, distributed and revised in accordance with document control cGMP"s.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2002

Mr. Mark S. Alsberge
VP Medical and Regulatory Affairs
Transonic Systems Inc.
34 Dutch Mill Road
Ithaca, NY 14850

Re: K010253
Tansonic Angio Flow Meter and Catheter
Regulation Number: 870.2100
Regulation Name: Cardiovascular blood flow-meter.
Regulatory Class: Class II
Product Code: 74 DYG
Dated: December 17, 2001
Received: December 20, 2001

Dear Mr. Alsberge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010253
Device Name: Transonic Angio Flow Meter and Catheter
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(Division Sign-Off)
Division of Cardiovascular
and Neurological Devices
510(k) Number K010253

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)